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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/493,545 01/28/00 ZHANG

R GI 5340A

EXAMINER

HM12/0809

American Home Products Corporation  
Patent & Trademark Department 2B  
Attn Barbara A Gyure  
One Campus Drive  
Parsippany NJ 07054

ROBINSON, P

ART UNIT

PAPER NUMBER

1653

DATE MAILED:

08/09/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Office Action Summary**

Application No.

09/493,545

Applicant(s)

ZHANG ET AL

Examiner

Patricia A. Robinson

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1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5,8,9 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps in the method claims are: the amount of the composition to be administered and the duration of the treatment necessary to achieve desired effect, either a specific dosing range or an "effective amount" and a duration of treatment is required in order for the method to be complete. In all the above recited claims, the amount of the active ingredient is unclear and/or unstated in the claim, e.g., ". . . an amount effective to effect . . . regeneration . . ."

Claims 5, 7, 12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 12 recite a purified proteins "BIP", "GDF" and "Vgr-2" but the claim fails to first spell-out fully what this abbreviation represents, thus it is unclear and confusing what "BIP" means. Therefore, the claims as written are indefinite.

Claims 7 and 14 recite "MP52" as a protein capable of inducing the formation of tendon or ligament-like tissue, however the claim fails to first fully spell-out what "MP52"

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represents, thus it is unclear and confusing what the abbreviation is meant to represent.

Therefore, the claims as written are indefinite.

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hattersley et al. which teaches compositions comprising BMP-2 and other growth and differentiation factors (transforming factor beta superfamily members) useful in methods of repairing articular cartilage, as well as in inducing cartilage formation. (See col. 1, lines 9-24; col. 2, lines 30-63; col. 3, lines 2-31; and col. 4, line 50- col. 5, line 4). Hattersley et al. also teaches that protein compositions comprising BMP-2 and BMP-13 are useful in methods of inducing the formation of other types of tissues, such as tendons and ligaments. (See col. 5, lines 25-47).

### ***Conclusion***

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Klein-Nulend et al. and Boyan et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Robinson whose telephone number is 703-305-0096. The examiner can normally be reached on 8:00 - 4:30 Monday - Friday, off alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 703-308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

PAR  
August 7, 2000

*Christopher S. F. Low*  
CHRISTOPHER S. F. LOW  
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